

Rectogesic® 4mg/g Rectal Ointment

(glyceryl trinitrate)

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor or pharmacist.
- * The information in this leaflet applies only to Rectogesic 4mg/g Rectal Ointment.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- * If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1 What Rectogesic is and what it is used for
- 2 Before you use Rectogesic
- 3 How to use Rectogesic
- 4 Possible side effects
- 5 Storing Rectogesic
- 6 Further information

1 What Rectogesic is and what it is used for

Rectogesic is a rectal ointment which contains the active substance glyceryl trinitrate. Glyceryl trinitrate belongs to a group of medicines called organic nitrates.

The ointment will help to relieve the symptoms of pain caused by chronic anal fissures. An anal fissure is a tear in the skin lining the anal canal. Topical application of glyceryl trinitrate to the anal canal reduces the anal pressure and increases the blood flow, thereby reducing pain.

2 Before you use Rectogesic

Do not use Rectogesic:

- * if you are allergic to glyceryl trinitrate or to similar medicines
- * if you are allergic to any of the other ingredients in the product
- * if you suffer from low blood pressure
- * if you suffer from heart or blood vessel disorder
- * if you suffer from closed-angle glaucoma - a condition where pressure inside the eye rises rapidly causing loss of vision
- * if you suffer from migraine or recurrent headaches
- * if you suffer from increased intracranial pressure or high pressure within your skull (e.g. head trauma or cerebral haemorrhage - bleeding from a ruptured blood vessel in the brain that can be fatal without prompt medical treatment. Cerebral haemorrhage is commonly referred to as a type of stroke) or inadequate cerebral circulation (low volume of blood circulation within your brain)
- * if you suffer from anaemia (low iron content in your blood)
- * if you are taking any of the following medicines: sildenafil citrate, tadalafil, vardenafil, medicines for angina or heart pain such as glyceryl trinitrate (GTN), isosorbide dinitrate, amyl or butyl nitrite, medicines for high blood pressure or depression (tricyclic anti-depressants), acetyl cysteine or alteplase

Take special care with Rectogesic:

- * if you suffer from liver or kidney disease
- * if you are to be given heparin, close monitoring of your blood will be required as your dose of heparin may need to be altered. Please discuss with your doctor before stopping Rectogesic
- * if you also have haemorrhoids (piles) and notice more bleeding than usual, you should stop using Rectogesic and discuss this with your doctor.
- * If you get severe headaches when using Rectogesic, please tell your doctor. Your doctor will decide if you need to use a different amount of Rectogesic, or stop using it completely.

Rectogesic may lower your blood pressure. When getting up from a lying or sitting position, you should get up slowly, otherwise you might feel faint. Your blood pressure is more likely to be lowered if you drink alcohol whilst you are using Rectogesic.

Rectogesic is not suitable for children and adolescents under the age of 18 years because it has not been assessed in people in this age group.

Taking Rectogesic with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

The following medicines may increase the blood pressure lowering effects of Rectogesic

- * Medicines for depression (tricyclic anti-depressants)
- * Medicines for erectile dysfunction (male impotence) (sildenafil citrate, tadalafil, vardenafil)
- * Medicines for high blood pressure
- * Diuretics ("water tablets")
- * Commonly used tranquillizers
- * Medicines used to treat heart problems (isosorbide dinitrate and amyl or butyl-nitrite)

Other Medicines

- * Acetyl cysteine may increase the effect of Rectogesic on blood flow
- * The effect of heparin (used to control blood clotting) may be decreased when used with Rectogesic
- * The effect of alteplase (used to treat heart problems) may be reduced when given at the same time as Rectogesic
- * Taking Rectogesic with dihydroergotamine (used to treat migraine) may increase the action of dihydroergotamine and lead to coronary vasoconstriction (narrowing of the blood vessels in the heart causing slower blood flow)
- * Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (certain types of painkillers) might lower the therapeutic effect of Rectogesic

Taking Rectogesic with food and drink

Be careful about drinking alcohol as the ointment may affect you more than usual.

Pregnancy and breast-feeding

You should not use Rectogesic during pregnancy or when breast-feeding. Ask your doctor or pharmacist for advice before taking any medicines when pregnant or breast feeding.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed with Rectogesic 4mg/g Rectal Ointment. If you feel dizzy, sleepy or have blurred vision when you start to use the ointment, do not drive or work machinery until these effects have worn off.

Important information about some of the ingredients of Rectogesic

This medicines product contains lanolin (wool fat) which may cause a skin reaction (e.g. contact dermatitis). The product also contains propylene glycol which cause skin irritation.

3 How to use Rectogesic

Method of Administration

Rectogesic 4mg/g Rectal Ointment is for Rectal Use.

Always use Rectogesic exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is approximately 375mg of ointment (approximately 1.5mg glyceryl trinitrate) applied to the anal canal every 12 hours.

Rectogesic® 4mg/g Rectal Ointment

(glyceryl trinitrate)

Patient Information Leaflet (continued)

A finger covering, such as cling film or a finger cot, may be placed on the finger to be used to apply the ointment. Finger cots can be obtained from your local pharmacy or surgical supplies retailer or cling film from your local store. The covered finger is placed alongside the 2.5cm dosing line, which is provided on the carton, and a strip of ointment the length of the line is expressed onto the end of finger by gently squeezing the tube. Gently insert the ointment into the anal canal using the finger. The finger with ointment must be inserted to the first finger joint (approximately 1 cm) into the anus.

Apply the ointment every twelve hours as directed by your doctor and do not exceed the dose. Wash hands after use and dispose of the finger cot or plastic wrap (not down the toilet).

Treatment may be continued until the pain goes away, or for up to a maximum 8 weeks. If your anal pain does not get better after using Rectogesic you should talk to your doctor again to check that something else is not causing the pain.

If you use more Rectogesic than you should

If you may have used more ointment than you should you may feel dizzy and light-headed. You may also have fast heart beats or palpitations. If you feel these symptoms wipe away any extra ointment and then talk to your doctor or pharmacist immediately.

If you forget to apply Rectogesic

Do not use a double dose to make up for forgotten individual doses. Apply the next dose at the usual time.

If you have any further questions on the use of Rectogesic, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Rectogesic can have side effects, although not everyone gets them. Tell your doctor if you notice any of the following:

Very Common (occur in more than 1 patient in 10)

- * Headaches, which may be severe. If you develop a headache as a side effect, wipe off any ointment. If the headaches are unpleasant, you may need to ask your doctor whether you should stop using the medicine.

Common (occur in more than 1 in 100 patients, but less than 1 in 10 patients)

- * Dizziness, faintness on standing, light-headedness, blurred vision and tiredness
- * Nausea

Uncommon (occur in more than 1 in 1000 patients but less than 1 in 100 patients)

- * Diarrhoea, anal discomfort, vomiting, rectal bleeding, rectal disorder
- * Allergic skin reactions (potentially severe)
- * Anaphylactoid reaction (allergic reaction, potentially fatal with face, lip, tongue or throat swelling, difficulty breathing, shortness of breath or collapse). **If you experience any of these symptoms stop using the ointment and seek medical attention immediately.**
- * Itching or burning of the anal canal
- * Fast heart beat or palpitations
- * Chest pain (angina)
- * Flush
- * Methaemoglobinaemia (non-functional red blood cells leading to an decrease in blood oxygen content)
- * Fainting

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also

report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 Storing Rectogesic

Keep out of the sight and reach of children.

Do not use Rectogesic after the expiry date which is stated on the box/tube label after the letters EXP. The expiry date refers to the last day of the month.

Do not store above 25°C., Do not freeze. Keep tube tightly closed.

Once opened use up the ointment within 8 weeks

6 Further information

What Rectogesic contains:

The active substance is glyceryl trinitrate. One gram of rectal ointment contains 40mg glyceryl trinitrate in propylene glycol corresponding to 4 mg glyceryl trinitrate. Approximately 1.5mg glyceryl trinitrate is contained in the usual 375 mg dose of Rectogesic.

The other ingredients are: propylene glycol, lanolin, sorbitan sesquioleate, hard paraffin and white soft paraffin.

What Rectogesic looks like and contents of the pack

Rectogesic is an off-white smooth opaque rectal ointment supplied in 30g aluminium tubes.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Manufacturer by:

PHARBIL Waltrop GmbH, Im Wirrigen 25, 45731 Waltrop, Germany

Rectogesic is a registered trademark of Strakan International Limited.

Revision date: 06/02/2015

POM PPA1562/147/001

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited, Tel: +44 (0) 1527 505414 for help.